enabling an administrator to define a plurality of clinical trial parameters through filling out fields in a set of computer forms;

storing the clinical trial parameters in a central database;

enabling clinical trial site personnel to enter subject enrollment data corresponding to at least one clinical trial defined by the clinical trial parameters via an Internet web portal;

storing the subject enrollment data in the central database substantially as it is entered in time; and

generating a chart displaying selected data aggregated from the subject enrollment data to graphically portray subject enrollment attributes pertaining to a selected clinical trail from among said at least one clinical trial.

Please add new claims 2-24 as follows.

--2. The method of claim 1, wherein the selected data are aggregated across an entire protocol corresponding to the selected clinical trial.

3. The method of claim 1, wherein the selected data correspond to an individual site that implements a protocol corresponding to a clinical trial.

4. The method of claim 1, wherein the administrator is enabled to define regions corresponding to a clinical trial protocol, each region corresponding to one or more sites that perform subject tests defined by a clinical trial protocol, and the selected data are aggregated across a selected region.

5. The method of claim 1, wherein the chart comprises an enrollment rate analysis chart that portrays a number of subjects newly enrolled for the selected

clinical trial during each of a plurality of periodic intervals using a selected aggregation level.

6. The method of claim 5, wherein the selected aggregation level corresponds to one of a site, a region comprising a plurality of sites, or a protocol comprising all of the sites used to perform a protocol corresponding to the selected clinical trial.

7. The method of claim 1, wherein the chart comprises a subject status analysis chart that portrays a plurality of subject status totals pertaining to the selected clinical trial and corresponding to a selected aggregation level.

A2 cont

8. The method of claim 7, wherein the selected aggregation level corresponds to one of a site, a region comprising a plurality of sites, or a protocol comprising all of the sites used to perform a protocol corresponding to the selected clinical trial.

9. The method of claim 1, wherein the administrator is enabled to define said plurality of clinical trial parameters using a computer that has a dedicated connection to the central database.

10. The method of claim 1, wherein the administrator is enabled to define said plurality of clinical trial parameters using a computer that stores corresponding data in a local database, further comprising synchronizing the local database with the central database such that data pertaining to said plurality of clinical trial parameters are copied to the central database.

11. The method of claim 1, wherein the computer forms are generated by rendering applets on a browser.

12. The method of claim 1, wherein the Internet web portal is supported by an application server hosting a plurality of software modules, including an object manager that interacts with a web engine to generate web-based forms including a plurality of fields that enable users of the Internet web portal to enter the subject enrollment data corresponding to said at least one clinical trial and a data manager that interacts with the object manager and a database server that hosts the central database to store data corresponding to the plurality of fields in the web-based forms.

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13. The method of claim 12, wherein the object manager includes a plurality of object classes and wherein the web-based forms comprise java-script based applets corresponding to a set of java-script object classes that substantially mirror respective object classes corresponding to the object manager.

14. The method of claim 1, further comprising:

providing a log-in mechanism to enable qualified users to access the Internet web portal;

identifying the user based on log-in data entered by the user that is authenticated against log-in information stored in the central database;

identifying any clinical trials the user is participating in as a member of an investigation team working on those clinical trials;

enabling the user to enter subject enrollment data pertaining to any clinical trials that are identified.

15. A method comprising:

defining parameters corresponding to a protocol for a clinical trial via a computer interface;

defining parameters corresponding to one or more sites that are used for conducting clinical trial tests based on the protocol via the computer interface;

storing the protocol and site parameters in a central database;

enabling clinical trial site personnel to enter subject enrollment data corresponding to the protocol via an Internet web portal;

storing the subject enrollment data in the central database substantially as it is entered in time via the Internet web portal;

generating a chart to graphically portray aggregated subject enrollment data pertaining to the protocol.

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16. The method of claim 15, further comprising defining regions for the protocol, each region comprising one or more sites.

17. The method of claim 16, wherein the chart depicts subject enrollment data that are aggregated across a selected region.

18. The method of claim 15, wherein the chart depicts subject enrollment data that are aggregated across an individual site.

19. The method of claim 15, wherein the chart depicts subject enrollment data that are aggregated across all sites for the protocol.

20. The method of claim 15, wherein the chart comprises an enrollment rate analysis chart that portrays a number of subjects newly enrolled for one of a site, region, or protocol during each of a plurality of periodic intervals.

21. The method of claim 15, wherein the chart comprises a subject status analysis chart that portrays a plurality of subject status totals pertaining to a selected aggregation level of protocol sites.

22. The method of claim 21, wherein the selected aggregation level corresponds to one of an individual site, a region comprising a plurality of sites, or all of the sites defined for the protocol.

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23. The method of claim 15, further comprising:

providing a log-in to enable qualified users to access the Internet web portal;

identifying the user based on log-in data stored in the central database;

identifying any protocols the user is participating in as a member of an investigation team working on those protocols;

enabling the user to enter subject enrollment data pertaining to any protocols that are identified.

24. The method of claim 15, wherein an administrator is enabled to define the protocol and site parameters using a computer that stores corresponding data in a local database, further comprising synchronizing the local database with the central database such that data pertaining to the protocol and site parameters are copied to the central database.--

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REMARKS

This Preliminary Amendment is to correct a grammatical error in claim 1 and add new claims 2-24 to a recently-filed application.